AUG 9 2012

5. 510(k) Summary as required by 21 CFR§807.92(c)

510(k) Owner: FCI SAS (France Chirurgie Instrumentation)
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Contact person: Barbara S. Fant, Pharm.D.
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Date: July 2, 2012

Trade Name: Crawford Bicanaliculus Intubation

Common name: Bicanalicular Nasal Probe
Bicanalicular Nasal Intubation Set

Classification Name: Lacrimal Stents and Intubation Sets

Product Code: OKS

Identification of a Legally Marketed Predicate Device
The Crawford Bicanaliculus Intubation is substantially equivalent to the Crawford Probe Intubation Set marketed by FCI Ophthalmics, Inc, 510(k) Premarket Notification Number: K991238, FDA Product Code OKS; and, to the Mono-Crawford Naso-Lacrimal Intubation Device marketed by FCI Ophthalmics, Inc, 510(k) Premarket Notification Number: K061404, FDA Product Code OKS.

General Description
The Crawford Bicanaliculus Intubation is a bicanalicular intubation device that consists of a silicone tube that is attached at each end to a flexible metallic Crawford probe. The Crawford Bicanaliculus Intubation comes in a single length of 310 mm and is provided as a sterilized product.

Intended Use
The Crawford Bicanaliculus Intubation stents are intended for use for nasolacrimal intubation in patients 12 months of age and older. Indications for nasolacrimal intubation performed with the Crawford Bicanaliculus Intubation are:

- Canalicular pathologies (e.g., congenital or acquired stenosis, lacerations)
- During dacryocystorhinostomy
- Congenital lacrimal duct obstruction

Comparison of Technological Characteristics
The Crawford intubation device was previously manufactured by a contract manufacturer and is now manufactured by FCI SAS. The Crawford Bicanaliculus Intubation manufactured by FCI SAS and the Crawford Probe Intubation Set manufactured by the contract manufacturer are identical in every respect except for the manufacturer and slightly different grades of silicone tube and stainless steel are used in the construction of each device. The Mono-Crawford Naso-Lacrimal Intubation Device is constructed of an identical silicone and stainless steel grade as the modified Crawford Bicanalicular Intubation device. All three devices have a stent body (tube) that is manufactured from an identical medical grade silicone tube (modified Crawford and Mono-Crawford) or from a very similar grade of silicone (Crawford primary predicate). The silicone used in the modified Crawford Bicanaliculus Intubation and Mono-Crawford is purchased as a silicone tube, which is then cut, and the gluing method is the same for these two devices. The silicone used in the Crawford primary predicate is extruded and then cut, and the gluing method is similar to the Crawford Bicanaliculus Intubation and Mono-Crawford. All three devices are ethylene oxide sterilized and provided in similar packaging. The stainless steel materials used in each device are medical grade with well characterized mechanical and biocompatibility properties.

Brief Summary of NonClinical Tests and Results
The technology transfer was validated, and demonstrated the capacity of FCI to manufacture the Crawford Bicanaliculus Intubation. Tensile strength tests were performed on samples before and after sterilization to validate the change in silicone grade and gluing method for the Crawford Bicanaliculus Intubation. All nonclinical test results met the established specifications for the device. The biocompatibility of the silicone raw materials and finished, sterilized device was tested to the applicable standards and met required specifications. Ethylene oxide sterilization validation studies and package integrity studies were performed according to the applicable standards; and, the test results support the shelf-life and storage conditions for the device.

Basis of Substantial Equivalence
The Crawford Bicanaliculus Intubation is substantially equivalent to the Crawford Probe Intubation Set and to the Mono-Crawford Naso-Lacrimal Intubation Device in material, intended use, basic design concept, dimensions, sterilization methods, and biocompatibility, and which are all manufactured by (or for) FCI SAS and distributed in the U.S.A. by FCI Ophthalmics, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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France Chirurgie Instrumentaion SAS
c/o Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
3308 Jefferson Ave., Upper Level
Cincinnati, OH 45220

Re: K121142
Trade/Device Name: Crawford Bicanaliculus Intubation
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: OKS
Dated: July 2, 2012
Received: July 3, 2012

Dear Dr. Fant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological, and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K121142

Device Name: Crawford Bicanaliculus Intubation

Indications for Use:

The Crawford Bicanaliculus Intubation stents are intended for use for nasolacrimal intubation in patients 12 months of age and older. Indications for nasolacrimal intubation performed with the Crawford Bicanaliculus Intubation are:

- Canalicular pathologies (e.g., congenital or ac quired stenosis, lacerations)
- During dacryocystorhinostomy
- Congenital lacrimal duct obstruction

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K121142